REMARKS

In the instant Final Office Action, claims 1-19 are listed as pending and all claims stand rejected. Claim 1 is amended to include the limitation that the compound binding to SSTR5 binds selectively to the SSTR5 receptor, that is, the Ki value of the compound to the SSTR5 receptor is at least 2.5 times greater than the Ki value of the compound to the SSTR2 receptor. Support for this amendment may be found in the specification at page 2 lines 18 to 21, page 4 lines 26 to 35, page 6 line 35 through to page 7 line2, page 7 lines 17 to 23, and in the data of Tables I and II and Figures 1-3. No claims are canceled and no new claims are added.

Applicants are grateful for the entry of the amendments and Terminal Disclaimer filed April 20, 2007 and subsequent withdrawal of the nonstatutory obviousness-type double patenting rejection.

1. Claim Rejections – 35 U.S.C. § 103(a)

1A) Rejection of claims 1-3, 5, 7-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a)

On pages 2-4 of the Instant Action, the Examiner maintains the rejection of claims 1-3, 5, 7-11, 13, 15, 16 and 18 as being unpatentable in light of Inoue (Horm. Metab. Res., 1992, 24:251-253; referred to hereinafter as Inoue) taken with Moore (Biochem. Biophys. Res. Comm., 1991, 179:1-9; referred to hereinafter as Moore) and Yamada (Birham Biophys. Res. Comm., 1993, 195:844-852; referred to hereinafter as Yamada).

The Examiner maintains the allegation that it would have been obvious to use the method of Yamada "for determining binding compounds for SSTR5, followed by evaluation of the biological effects of SSTR5 compounds using the method of Moore or Inoue to inhibit amylin secretion in pancreatic cells . . .". The Examiner concludes that this combination of references hinges upon Yamada suggesting "use of somatostatin subtypes (e.g. SSTR5 agonists) should reveal the molecular bases for somatostatin

function, which includes exocrine and endocrine function (e.g., amylin inhibition) in the pancreas, pituitary and GI tract."

Additional details of the Examiner's reasoning and rejection are found on pages 2-4 of the instant Action and are not reiterated in full in this reply.

1B) Amendments to the claims

Claim 1 is amended in this reply.

1C) Claims 1-3, 5, 7-11, 13, 15, 16 and 18 are not obvious in light of Inoue, Moore and Yamada

Applicants respectfully submit that the Examiner has failed to meet the basic CAFC requirement that an obviousness rejection be supported by some suggestion in the prior art to create the claimed invention:

> [A] proper analysis under §103 requires, *inter alia*, consideration of . . . whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed invention,

In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) (emphasis added).

Applicants submit that Yamada teaches a fourth (SSTR4) and a fifth (SSTR5) somatostatin receptor along with methods to determine if a candidate somatostatin compound binds to either SSTR4 or SSTR5. Moore teaches that somatostatin, which binds to all 5 somatostatin receptors, can decrease amylin secretion, a finding further supported by Inoue. Applicants submit, however, that neither Moore nor Inoue teach or suggest that of the five SST receptors, activity at the SSTR5 sub-type receptor is responsible for the reduction in amylin secretion. This defect is not remedied by Yamada as Yamada simply teaches the discovery of two new somatostatin receptor sub-types and a means for determining if an analog binds to the discovered receptors.

The combination of Yamada, Inoue and/or Moore fails to teach or suggest that a preferred somatatostatin analog useful for inhibiting the secretion of amylin is an SSTR5 selective analog exhibiting a Ki value at the SSTR5 receptor that is at least 2.5 times greater than the Ki value of the same analog at the SSTR2 receptor. There is no teaching or suggestion in the combination of Yamada, Inoue and/or Moore that would direct the

skilled artisan to select somatostatin analogs selective for SSTR5 from amongst analogs binding to the other SST receptors. Applicants submit that the combination of Yamada, Inoue and/or Moore fails to meet the "should" make the invention requirement of a proper 103(a) rejection.

As further detailed by the CAFC a "proper obviousness analysis requires consideration of whether the prior art would also have revealed that in so making or carrying out [the claimed invention], those of ordinary skill would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

In light of the amendments presented herein, Applicants respectfully submit that there are no teachings in Yamada, Inoue and/or Moore which would have led the skilled artisan to expect that an SSTR5 selective agonist would decrease amylin secretion any better than an agonist to SSTR1, SSTR2, SSTR3 and/or SSTR4. Again, Moore and Inoue only demonstrate that somatostatin, which binds to all 5 receptor subtypes, can decrease amylin but neither reference points out which of the 5 receptors is activated to achieve the observed decrease in amylin levels. Moore cannot rectify this defect as Moore offers no data to teach or suggest that a somatostatin agonist binding at any SSTR receptor can affect amylin secretion. It is Applicants discovery that compounds selective for SSTR5 are those somatostatin agonists which affect amylin secretion. Applicants submit that the combination of Yamada, Inoue and/or Moore fails to meet the "expectation of success" requirement of a proper 103(a) rejection.

As recited in the MPEP at 2143.03, "to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F2.d 981, 180 USPQ 580 (CCPA 1974)". Applicants respectfully submit that, as reasoned above, neither Yamada, Inoue and/or Moore, either alone or in combination, teach all aspects of Applicants' claimed invention. This combination of references fails to teach or suggest Applicants discovery that SSTR5 selective agonists, that is, those compounds which bind to SSTR5 with a Ki value at least 2.5 times greater than the Ki value for that compound at SSTR2, trigger a decrease in the levels of amylin.

Applicants submit that the combination of Yamada, Inoue and/or Moore fails to meet the "teaches all aspects of the claims" requirement of a proper 103(a) rejection.

1D) Request for withdrawal of rejection of claims 1-3, 5, 7-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a)

Applicants submit that, for reasons and amendments cited above, claims 1-3, 5, 7-11, 13, 15, 16 and 18 are not obvious in light of Inoue, Moore and Yamada. Applicants respectfully submit that the rejection of claims 1-3, 5, 7-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a) has been obviated. Applicants respectfully request that said rejection be withdrawn.

2. Claim Rejections – 35 U.S.C. § 103(a)

2A) Rejection of claims 1-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a)

On pages 4-5 of the Instant Action, the Examiner rejects claims 1-11, 13, 15, 16 and 18 as being unpatentable in light of Inoue (Horm. Metab. Res., 1992, 24:251-253; referred to hereinafter as Inoue) and Moore (Biochem. Biophys. Res. Comm., 1991, 179:1-9; referred to hereinafter as Moore) taken with Yamada (Birham Biophys. Res. Comm., 1993, 195:844-852; referred to hereinafter as Yamada) and further taken with Hoyer (Arch. Pharm., 1994, 350:441-453, referred to hereinafter as Hoyer).

The Examiner alleges that it would have been obvious to use Hoyer's cell preparations of rat olfactory bulb cells expressing SSTR5 or CHO-K1/SSTR5 cells or Hoyer's somatostatin agonists with the method of Yamada combined with the methods of Moore or Inoue to first determine the ability of a compound to bind to a somatostatin type-5 receptor, and, if and only if the compound bound an SSTR5 receptor, to go on and determine if that compound inhibited amylin release from amylin-secreting pancreas cells. The details of the Examiner's reasoning and rejection are found on pages 4-5 of the instant Action and are not reiterated in full in this reply.

2B) Amendments to the claims

Claim 1 is amended in this reply.

2C) Claims 1-3, 5, 7-11, 13, 15, 16 and 18 are not obvious in light of Inoue, Moore, Yamada and Hoyer

Applicants respectfully submit that the method of instant claims 1-11, 13, 15, 16 and 18 is not obvious in light of Inoue, Moore and Yamada in further view of Hoyer. As discussed above, Applicants submit that Inoue, Moore and Yamada fail to teach or suggest a method of determining the ability of a compound to *selectively* bind to a somatostatin type-5 receptor with a Ki value at least 2.5 times greater than the Ki value of the same compound at a somatostatin type-2 receptor and to select such a compound from all other compounds binding to any of the five SSTR receptors, and, if and only if the compound met such criteria, to go on and determine if that compound inhibited amylin release from amylin-secreting pancreas cells. Applicants submit that Hoyer fails to teach or suggest a link between a compound binding to SSTR5 and the inhibition of amylin release, and thus cannot overcome the failings in the teachings of Inoue, Moore and Hoyer.

2D) Request for withdrawal of rejection of claims 1-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a)

Applicants submit that, for reasons and amendments cited above, claims 1-11, 13, 15, 16 and 18 are not obvious in light of Inoue, Moore and Yamada in view of Hoyer. Applicants respectfully submit that the rejection of claims 1-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a) has been obviated. Applicants respectfully request that said rejection be withdrawn.

Applicants submit that the claims are now in a condition for allowance. Reconsideration of the instant Office Action, entry of the amendments submitted herewith, and allowance of all pending claims are respectfully requested. Prompt and favorable action is solicited.

Respectfully submitted,

Date:
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Pamela C Ball

Pamela C. Ball
Agent for Applicant(s)
Reg. No. 53,963

Biomeasure, Incorporated
27 Maple Street
Milford, MA 01757-3650
(508) 478-0144 Telephone
(508) 478-2530 Facsimile